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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,983	06/26/2001	Dinesh O. Shah	6821.US.01	9651

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EXAMINER	
WORTMAN, DONNA C	
ART UNIT	**PAPER NUMBER**
1648	23

DATE MAILED: 04/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/891,983	SHAH ET AL.	
	Examiner	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 18-21* is/are pending in the application.

4a) Of the above claim(s) *18-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15 and 18-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *18* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 1, 2, 3, 8, 9, 10 and 13 were amended and claims 16, 17 and 22 were canceled in Paper No. 20. Claims 10 and 14 were amended in Paper No. 22. Claims 18-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

Claims 1-15 are under examination.

Claim 8 is objected to because of the following informalities: Claim 8, step b) makes reference twice to "(a)(1)" and twice to "(a)(2)" but the preceding parts of the claim are actually designated as "a) 1)" and "a) 2)." The use of consistent punctuation is suggested.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it is drawn to a method of simultaneously detecting at least one hepatitis C virus antigen and at least one HCV antibody, but does not clearly recite any "detecting" step; lacking a detecting step, the claim is incomplete. Claim 1 is further indefinite because it is not clear whether "mixture" refers to a mixture of antigen and antibody used to coat a single solid phase, or a mixture of antigen-coated solid phase and antibody-coated solid phase. Claim 1 is also confusing because it appears to require two separate

correlation steps ("presence of said antibody/antigen complexes indicating presence of said at least one HCV antibody" and "presence of said antigen/antibody complexes indicating presence of said at least one HCV antigen") but it is not clear whether the method intends that two separate signals, representing each of the two complexes, be detected separately but simultaneously, or that a single signal be detected, representing the presence of the first and/or the second type of complex.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is evident that monoclonal antibodies 107-35-54, 110-81-17, 13-975-157, 14-1350-210, C11-3, C11-7, C11-10, and C11-14 are all required in order to practice the claimed invention since each is specifically recited. Applicant must either comply with the biological deposit rules as set out in 37 CFR 1.801 - 1.809 or demonstrate that each antibody is well-known and readily available to the public. Every member of a Markush group must be enabled.

Applicant has argued that since hybridoma cell lines 107-35-54 (referred to as H35C54), 110-81-17, 13-975-157, and 14-1350-210 are disclosed in US Patent No. 5,753,430, and since hybridoma cell lines HC11-14, HC11-10, HC11-

3, and HC11-7 are disclosed in PCT application WO 00/07023 and were deposited as FERM BP-6006, FERM BP-6004, FERM BP-6002 and FERM BP-6003, all the monoclonal antibodies are well-known and readily available to the public.

This argument has been considered and found persuasive in part, *viz.*, with respect to the hybridoma cell lines deposited as FERM BP-6006, FERM BP-6004, FERM BP-6002 and FERM BP-6003. Applicant is requested to point out where each of the cell lines 107-35-54 (referred to as H35C54), 110-81-17, 13-975-157, and 14-1350-210 and its corresponding ATCC number, if any, are disclosed in US Patent No. 5,753,430 since numerous cell lines are mentioned in the patent disclosure and it is not readily apparent that the designations and deposited material are the same as the cell lines recited in the instant application specification and claims.

The prior art rejections as previously set forth and applied to claims 16, 17 and 22 are withdrawn in view of Applicant's cancellation of claims 16, 17, and 22. The rejection under 35 USC 102(b) of claims 1 and 2 over Jolivet-Reynaud et al. is withdrawn because claim 1 is indefinite as explained above. The rejection under 35 USC 103(a) over Dawson et al. in view of Masalova et al. is withdrawn for claims 1-7 because claim 1 is indefinite as discussed and for claims 8-11 and 13 in view of Applicant's argument that Dawson's disclosure of "co-detection" does not mean a simultaneous detection system, but rather the detection of both antibodies and antigens in different assays, which argument has been carefully considered and found persuasive. The rejection under 35 USC 103(a) over

O'Connor et al. in view of Masalova et al. is withdrawn because claims 1-7 are indefinite as discussed, and in light of Applicant's argument that the method of O'Connor et al. produces two distinguishable signals, which argument is found persuasive with respect to claims 8-15.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Publication No. 2002/0192639 A1, Chien et al., now cited on PTO 892, attached. Chien et al. disclose kits comprising an HCV antigen and an HCV antibody coated on a single solid phase and conjugates comprising a signal-generating compound, anticipating the claimed subject matter. See, e.g., the Abstract and Fig. 2.

Claims 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Publication No. 2003/0049608 A1, Bahl et al., now cited on PTO 892, attached. Bahl et al. disclose kits comprising an HCV antigen and an HCV antibody coated on a single solid phase and conjugates comprising a

signal-generating compound, anticipating the claimed subject matter. See, e.g., the Examples and claim 6.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13 and 14 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Aoyagi et al., US Patent Publication No. 2002/0173493 A1, cited by Applicant on PTO 1449 submitted as Paper No. 18. The composition of Aoyagi comprising a container containing an HCV antigen and an HCV antibody coated on a solid phase and a conjugate comprising a signal-generating compound is believed to anticipate the subject matter of claims 13 and 14 although it is not explicitly referred to as a "kit"

but if not, it would have been obvious to package the composition in form of a kit as is conventionally done for reasons of convenience and economy.

Claims 8-11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoyagi et al. as cited above. Aoyagi discloses a method for simultaneously detecting the presence of at least one HCV antigen and at least one HCV antibody using at least one HCV antigen and at least one HCV antibody, which may be C11-3, C11-7, C11-10, and/or C11-14, coated on a single solid phase, and using conjugates comprising antibodies attached to the same signal generating compound and detecting the generated signal. The method of Aoyagi differs from the claimed method only by exemplifying the use of an enzyme label in place of a chemiluminescent label such as acridinium. It would have been obvious to one of ordinary skill in the art, based on the teachings of Aoyagi, to have used a chemiluminescent label because Aoyagi teaches that any conventional label may be used (see, e.g., Aoyagi, page 3, [0039]).

Claims 8-11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chien et al. as cited above. Chien discloses a method for simultaneously detecting the presence of at least one HCV antigen and at least one HCV antibody using at least one HCV antigen and at least one HCV anti-core antibody, coated on a single solid phase, and using conjugates comprising antibodies attached to the same signal generating compound and detecting the generated signal. Chien specifically lists suitable labels, including chemiluminescers such as dimethyl acridinium ester (see, e.g., page 8, [0075]).

It would have been obvious to one of ordinary skill in the art, based on the teachings of Chien, to have detected both HCV antigen and antibody simultaneously, using a single solid phase coated with HCV antibody and HCV antigen and antibody-chemiluminescent compound conjugates to generate a detectable signal, because Chien exemplifies an assay using the same format as claimed and suggests the use of a chemiluminescent label.

Claims 8-12, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bahl et al., in view of Chien et al., both cited above. Bahl teaches a combination HCV HCV core antigen and antibody assay and teaches that HCV core antigen and HCV antibodies of different types may be detected either together or separately (see, e.g., [0011] and Examples. Bahl further teaches that anti-core monoclonal antibodies C11-3 and C11-7 may be used. The method of Bahl differs from the claimed method only by exemplifying the use of an enzyme label in place of a chemiluminescent label such as acridinium. Chien et al. teaches that any conventional label, including acridinium, can be used in an HCV antigen-antibody combination assay. It would have been obvious to one of ordinary skill in the art to have substituted a chemiluminescent label as taught by Chien for the exemplified enzyme of Bahl et al. because Bahl et al. requires only a "detectable label" (see, e.g., Bahl et al., claim 8) and because Chien teaches that any conventional label, including a chemiluminescent label, can be used in an HCV antigen-antibody combination assay.

Claims 12, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dawson et al., Transfusion, October 2000, in view of Masalova et al., both of record. Dawson discloses co-detection of HCV core antigen and HCV antibodies in a chemiluminescent assay but do not specifically disclose a solid-phase immunoassay format or kits. Masalova et al. disclose the use of a solid-phase HCV immunoassay format for sandwich immunoassays. While neither Dawson nor Masalova specifically disclose kits, it would have been obvious to one of ordinary skill in the art at the time the invention was made to package two solid phase components to be used together in the form of a kit for reasons of convenience and economy; such components are necessarily kept in containers.

Applicant's argument that the "co-detection" assay of Dawson represents two separate assays performed at the same time does not serve to distinguish compositions for carrying out two separate assays at the same time from the kit as instantly claimed.

Because claim 1 is indefinite is discussed above, no prior art rejection is offered for claims 1-7, since it is not clear what assay format Applicant intends to claim.

Because this action contains new grounds of rejection, it is made non-final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone

number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
April 28, 2003